Drug Safety Oversight Board Roster

Chair (Non-voting)

 Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs Center for Drug Evaluation and Research

Acting Executive Director (Non-voting)

• Terry Toigo, RPh, MBA Acting Executive Director of the Drug Safety Oversight Board, Associate Director for Drug Safety Operations, Center for Drug Evaluation and Research

Center for Drug Evaluation and Research

Primary Member:

- Robert Temple, M.D., Deputy Director for Clinical Science
- Richard Moscicki, M.D., Deputy Director of Science Operations

Office of New Drugs, Center for Drug Evaluation and Research

Primary Members:

- Mwango Kashoki, M.D., M.P.H., Associate Director for Safety, Office of New Drugs
- Mary Parks, M.D., Director, Division of Metabolism and Endocrinology Products Alternate Members:
- John Jenkins, M.D., Director, Office of New Drugs
- Sandra Kweder, M.D., Deputy Director, Office of New Drugs
- Ellis Unger, M.D., Director, Office of Drug Evaluation 1

Office of Medical Policy, Center for Drug Evaluation and Research

- Patrick Archdeacon, M.D., Medical Officer
- Richardae Araojo, Pharm. D. MS, CDR USPHS, Deputy Director, OMP

Office of Generic Drugs, Center for Drug Evaluation and Research

Primary Member:

• Linda Forsyth, M.D., Division of Clinical Review

Alternate Member:

• Shewit Bezabeh

Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research Primary Members:

• Mark I. Avigan, M.D., Associate Director for Critical Path Initiatives,

Alternate Member:

• Gerald DalPan, M.D., M.H.S., Director

Office of Pharmacovigilance and Epidemiology

Primaries:

- Judy Staffa, Ph.D., R.Ph., Acting Associate Director for Regulatory Research
- Culin Wang, M.D., Director of Epidemiology I
- Robert Levin, M.D., Acting Director, Division of Pharmacovigilance I
- Scott Proestel, M.D., Director, Division of Pharmacovigilance II

Alternate:

• Solomon Iyasu, M.D., Director, Office of Pharmacovigilance and Epidemiology

Office of Medication Error Prevention and Risk Management

Primary Members:

- Todd Bridges, RPh, Deputy Director
- Cynthia LaCivita, RPh, Acting Director, Division of Risk Management

Alternate Members:

- Kellie Taylor, PharmD, Deputy Director
- Claudia Manzo, PharmD, Acting Director

Office of Translational Sciences, Center for Drug Evaluation and Research

Immediate Office

Primary Member:

• TBD

Alternate Member:

• ShaAvhree Buckman, M.D., Ph.D., F.A.A.P. Acting Director, Office of Translational Sciences

Office of Biostatistics

Primary Member:

• Aloka Chakravarty, Ph.D., Director, Division of Biometrics

Alternate Member:

• Mark Levenson, Ph.D., Deputy Director, Division of Biostatistics 7

Office of Clinical Pharmacology

Primary Member:

 Darrell Abernethy, M.D., Ph.D., Associate Director of Drug Safety, Office of Clinical Pharmacology

Alternate Member:

• Keith K. Burkhart, M.D., FACMT, Senior Advisor for Medical Toxicology Predictive Safety Team

Office of Communications

Primary Member:

• Kimberly A. Rawlings, Acting Director

Alternate Member:

• Mary E. Kremzner, PharmD, MPH, CAPT, USPHS, Acting Deputy, Office of Communications

Office of Compliance, (CDER)

Primary Member:

- Ilisa B.G. Bernstein, Pharm. D., J.D., Acting Deputy Director, Office of Compliance Alternate Member:
- Charles E. Lee, M.D., CAPT, USPHS, Div. of New Drugs and Labeling Compliance, Office of Compliance

Office of the Center Director, Center for Drug Evaluation and Research

Primary Member:

• John Whyte, MD, MPH, Director of Professional Affairs and Stakeholder Engagement, Office of the Center Director

Alternate Member:

Office of Pharmaceutical Science, Center for Drug Evaluation and Research

Primary Member:

• Samia M. Nasr, R.Ph. M.S.

Alternate Member:

TBD

Center for Biologics Evaluation and Research, Food and Drug Administration Primary Member:

• Steven Anderson, Ph.D.,M.P.P., Acting Director, Office of Biostatistics Alternate Member:

• David Martin, MD., M.P.H., Acting Director, Division of Epidemiology, Office of Biostatistics and Epidemiology

Center for Devices and Radiological Health, Food and Drug Administration Primary Member:

- Kimberly Brown Smith, MD, PhD, Office of Compliance, Clinical Team Leader Alternate Member:
- Robert L. Becker, Jr., M.D., Ph.D., Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety

Federal Partners

Agency for Healthcare Research and Quality

Primary Member:

- Scott R. Smith, Ph.D., Director, Pharmaceutical Outcomes Research, Center for Outcomes and Evidence
- Alternate Member: TBD

Centers for Medicare and Medicaid Services

Primary Member:

• Jeffrey A. Kelman, M.D., MMsc., Chief Medical Officer

Alternate Members:

- Judith A. Geisler, R.Ph., CHC, Director, Division of Formulary and Benefit Operations
- Monica Reed, PharmD., LT, USPHS, Division of Formulary and Benefit Operations

Centers for Disease Control and Prevention

Primary Member:

• Dan Budnitz, M.D., M.P.H., CAPT, USPHS, Director, Medication Safety Program, Division of Healthcare Quality Promotion

Alternate Member:

• Nadine Shehab, PharmD., M.P.H., Division of Healthcare of Quality Promotion

Department of Defense

Primary Member:

- William G. Davies, RPh., MS, Integrated Utilization Branch Chief, Pharmacy Operations Division, Defense Health Agency
- COL Trinka Coster, MD, MS, Director, Pharmacovigilance Center, Office of the Surgeon General, Department of the Army

Department of Defense (Clinical)

Primary Member:

• Walter M. Downs, MD, CAPT MC USN, Medical Consultant, Rheumatologist, Pharmacy Operations Division

Alternate Member:

- Michael Datena, CIV, OASD (HA) / TMA, Acting Assistant Chief of the Patient Safety Division
- Deborah Myers, RPh, MBA, Deputy Director, Patient Safety Analysis Center, Tricare Management Activity

Health Resources and Services Administration

Primary Member:

- Karen C. Williams, MBA, Pharm.D., Sr Program Mgmt Officer, Office of Pharmacy Affairs Alternate Member:
- Lawrence Momodu, Pharm.D., LT, USPHS, Office of Pharmarcy Affairs

Indian Health Service

Primary Member:

• Ryan Schupbach, Pharm. D., BCPS, CACP, NCPS, Commander, U.S., Public Health Service, Clinical Pharmacy Director & National Anticoagulation Training Program Director

Alternate Member:

• Matthew R. Baker, Pharm.D, BCPS, CDR United States Public Health Service, Supervisor Pharmacy Support Branch, IHS, National Supply Service Center

National Institutes of Health, National Cancer Institute

Primary Member:TBD

Alternate Member:

 Pamela Jo Harris, M.D.,F.A.C.P., Senior Investigator, Investigational Drug Branch, Cancer Therapy Evaluation Program

National Institute of Health, Office of Director

Primary Member:

• Jacqueline Corrigan-Curay, M.D., J.D., Acting Director, Office of Biotechnology Activities <u>Alternate Member: TBD</u>

Department of Veterans Affairs

Primary Member:

• C. Bernie Good, M.D., M.P.H., Chairman, Medical Advisory Panel for Pharmacy Benefits Management, Veterans Administration Pittsburgh Healthcare System

Alternate Members:

- Peter Glassman, MBBS, M.Sc., Staff Physician, Department of Veterans Affairs, VA Greater Los Angeles Healthcare System
- Walid F. Gellad, M.D., M.P.H., Department of Veterans Affairs, Veterans Administration Pittsburgh Healthcare System

Bureau of Prisons

Primary Member:

• RADM Chris Bina, PharmD, U.S. Assistant Surgeon General, Director, Pharmacy Program, Federal Bureau of Prisons, Health Services Division

Alternate Member:

• A. Martin Johnston, R.Ph., Captain, US Public Health Service Chief, Pharmacy Logistic Support, Federal Bureau of Prisons, Health Services Division